K121285

MAR 0 8 2013

SECTION 5
510(K) SUMMARY

1. Submitter's Name and Contact Information

Company Name:	New Jersey Snoring Solutions
Address:	769 Northfield Avenue, Ste 154 West Orange, NJ 07052
Contact Person:	Deborah Stein Vice President, New Jersey Snoring Solutions
Email:	debbie481@comcast.net
Telephone:	973-886-6855
Fax:	973-325-6442

Summary Preparation Date: January 14, 2013

2. Device Identification:

Proprietary Name:	Oravan OSA
Common Name:	Anti-snoring device
Classification:	Class II
Product Code:	LRK
Regulation Number:	21 CFR 872.5570
Review Panel:	Dental

3. Description of the Device:

The Oravan OSA has been developed for the treatment of mild to moderate obstructive sleep apnea. Each Oravan device is made for each individual patient. There are two unique acrylic pieces that fit over the top and bottom teeth. The Oravan is fully adjustable for maximum benefit to treat the symptoms of obstructive sleep apnea and snoring. The Oravan sleek design allows for comfortable mandibular movement. The Oravan is made of orthodontic acrylic. Each device is warranted for 2 full years against breakage from everyday use.

4. Indications for Use:

Oravan OSA is intended to reduce snoring and mild to moderate sleep apnea in adults

5. Predicate Devices:

The Oravan OSA is substantially equivalent to the following devices:

i. Somnomed MAS RxA (by Somnomed Ltd.), cleared under K050592
ii. The Moses Appliance (by Allen J. Moses, DDS, Ltd.), cleared under K093710

6. Summary of Similar Technological Characteristics

The proposed 'Oravan OSA' and the predicate devices are Anti-snoring devices intended to reduce snoring and mild to moderate sleep apnea in adults. Their fundamental scientific technology, design,t echnological characteristics and materials are also comparable, as outlined in the following table:

	Subject Device	**Predicate Device K093710**	**Predicate Device K050592**
	Oravan OSA	**The Moses Appliance**	**Somnomed MAS RxA**
	New Jersey Snoring Solutions	**Allen J. Moses, DDS, Ltd.**	**Somnomed Ltd.**
Characteristics / Features			
Indications for Use	Oravan OSA is intended to reduce snoring and mild to moderate sleep apnea in adults	The Moses appliance is intended for use on adult patients18 years of age and older as an aid for the reduction and/or alleviation of snoring and mild to moderate obstructive sleep apnea.	The SomnoMed MAS RxA is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.
Prescription / OTC Use	Prescription only Note: Custom-fitted to each patient, based on dental impressions	Prescription only Note: Custom-fitted to each patient, based on dental impressions	Prescription only Note: Custom-fitted to each patient, based on dental impressions
Device components/ parts	Orthodontic Acrylic trays Expansion Screws Wire with Ball clasp	Orthodontic Acrylic tray Expansion Screws Wire with Ball clasp	Orthodontic Acrylic trays Expansion Screws Wire with Ball clasp
Device configuration	Two-piece design: Upper acrylic tray covers top posterior teeth Lower acrylic tray covers bottom posterior teeth	One-piece design: Acrylic tray covers top and bottom posterior teeth In addition, a retainer is used for the top anterior teeth. No such retainer is required for the bottom anterior teeth.	Two-piece design: Upper acrylic tray covers top teeth (both posterior and anterior) Lower acrylic tray covers bottom teeth (both posterior and anterior)

	Subject Device	Predicate Device K093710	Predicate Device K050592
	Oravan OSA	The Moses Appliance	Somnomed MAS RxA
	New Jersey Snoring Solutions	Allen J. Moses, DDS, Ltd.	Somnomed Ltd.
Characteristics / Features			
Device Functionality	The device allows for increase in the patient's pharyngeal opening, improving their ability to exchange air during sleep and reduce vibrations. Works by mandibular advancement using component advancement screws. Extension wings hold maxillary and mandibular sections in relative approximation once advancement is fixed Ball clasps hold the device on teeth Lower jaw advancement is adjustable using a supplied adjustment key	The device allows for increase in the patient's pharyngeal opening, improving their ability to exchange air during sleep and reduce vibrations. Works by mandibular advancement using component advancement screws. Extension wings hold maxillary and mandibular sections in relative approximation once advancement is fixed Ball clasps hold the device on teeth Lower jaw advancement is adjustable using a supplied adjustment key	The device allows for increase in the patient's pharyngeal opening, improving their ability to exchange air during sleep and reduce vibrations. Works by mandibular advancement using component advancement screws. Extension wings hold maxillary and mandibular sections in relative approximation once advancement is fixed Ball clasps hold the device on teeth Lower jaw advancement is adjustable using a supplied adjustment key
Mandibular Advancement range	Up to 6 mm	Up to 6 mm	Up to 6 mm
Materials			
• Orthodontic Acrylic	Two part Polymethylmethacrylate; supplied by Dentaurum; (Medical grade, biocompatible)	Two part Polymethylmethacrylate; supplied by Dentaurum; (Medical grade, biocompatible)	Two part Polymethylmethacrylate; supplied by Dentaurum; (Medical grade, biocompatible)
• Colorants	No colorants	Blue	Pink
• Screws • Wire and ball clasp	Medical Grade Stainless Steel	Medical Grade Stainless Steel	Medical Grade Stainless Steel

7. Non-Clinical Data

The submission includes data regarding the physical properties of the Orthodontic Acrylic material used in the Oravan OSA. These physical properties are in accordance with the requirements and limits specified in standard ISO 20795-2:2005 - Dentistry -- Base polymers -- Part 2: Orthodontic base polymers.

8. Clinical Testing

The submission does not rely on any clinical data; therefore no clinical testing was performed

9. Conclusion:

Based on the intended use, design, technological characteristics and non-clinical information provided in the submission; the proposed 'Oravan OSA' is substantially equivalent to the predicate device, and does not raise any new concerns of safety of effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 8, 2013

Ms. Deborah Stein
Vice President
New Jersey Snoring Solutions
769 Northfield Avenue, Suite 154
WEST ORANGE NJ 07052

Re: K121285
Trade/Device Name: Oravan OSA
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: January 16, 2013
Received: February 7, 2013

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121285

Device Name: Oravan OSA

Indications for Use:

Oravan OSA is intended to reduce snoring and mild to moderate sleep apnea in adults

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner -S
Mary S. Runner -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____